

**REMARKS**

Claims 1-10 are all the claims pending in the application.

After entry of this amendment, claims 1, 2 and 8-10 will be canceled and claims 3-7 will be pending.

Claims 3-5 have been amended to limit the scope of the claims to the polypeptide of SEQ ID NO:14, and the polynucleotides encoding the polypeptide.

No new matter has been added. Entry of the amendment is respectfully requested.

**I. Formal Matters**

A. Applicants respectfully note that on the Office Action Summary sheet the Examiner mistakenly indicates that claims 3-7 are the only claims pending in the application. While claims 1, 2, and 8-10 are to the non-elected invention, they had not been canceled.

That being said, included herewith is an amendment to the claims, directing the cancellation of claims 1, 2 and 8-10, without prejudice or disclaimer to the re-filing of the cancelled claims in the context of a divisional application.

B. Applicants respectfully note that the Examiner has not acknowledged Applicants' claim to foreign priority or receipt of the priority document in this application.

Therefore, Applicants now request that the Examiner acknowledge the claim and receipt of the priority document, thus perfecting Applicants' claim to priority.

C. Applicants note that an Information Disclosure Statement was filed in this application, along with a Form PTO 1449, on November 14, 2000. As the Examiner has not yet returned a signed and initialed copy of the Form PTO 1449, Applicants respectfully request return of a copy of the appropriately acknowledged form.

**II. Rejection of the Claims Under 35 U.S.C. §101**

At paragraph 2 of the Office Action, claim 3-7 are rejected under 35 U.S.C. §101, as lacking either a specific and/or substantial utility or a well-established utility.

The Examiner asserts that the utilities of using the polynucleotides of the present invention as probes for use in isolation of full-length genes, gene mapping, isolation of homologous sequences, detection of gene expression, molecular weight markers, chromosomal markers, etc., are non-specific uses applicable to nucleic acids in general and not particular or specific to the nucleic acids being claimed.

The Examiner also states that the claims are rejected under 35 U.S.C. §112, first paragraph, as being non-enabled. The Examiner contends that if the claimed invention is not supported by either a specific and substantial utility, or a well-established utility, one skilled in the art would not know how to use the claimed invention.

In response, Applicants first note that the scope of the claims pending in this application have been limited to one polypeptide, namely OAF075b (SEQ ID NO:14), and to the polynucleotides encoding this protein (e.g., SEQ ID NOS:12 and 13).

As discussed at page 5, lines 8-10, of the specification, OAF075b is predicted to be a secretory protein due to the lack of a hydrophobic region, and it is expected to have the activity of human carboxypeptidase (A2) due to significant homology with this protein (as discussed at page 32, lines 13-18).

Enclose herewith is a reference article by Huang et al. (Cancer Research (1999))<sup>1</sup> which discloses the 421 amino acid polypeptide CPA3 (carboxypeptidase A3). As disclosed in Huang et al., CPA3 is useful as a marker of treatment of androgen-independent prostate tumor. Furthermore, it is a carboxypeptidase, which is a class of exopeptidases known to function in the digestion of peptides. Exopeptidases are well known as digestive enzymes, and they are secreted from the pancreas.

As also disclosed in Huang et al., when sodium butyrate was added to the androgen-independent prostate cancer cell line PC-3, the cells underwent apoptosis. CPA3 was found to be upregulated in these cells, through detection of genes expressed upon butyrate treatment. CPA3 was not detected in the pancreas. Furthermore, it was only detected at very low levels in a healthy person, and in androgen-sensitive prostate cancer cells. Thus, it was detected specifically when apoptosis is caused by administering BuNa and TSA. Thus, it is thought to function as a positive marker of treatment of androgen-independent prostate cancer.

Applicants also note that the use of a carboxypeptidase (prostate-specific antigen) as a diagnostic marker for prostate cancer is already known, as discussed in Chang et al.<sup>2</sup>

An alignment<sup>3</sup> of the amino acid sequence of OAF075b and CPA3 shows that OAF075b is an apparent variant of CPA3. The two polypeptides are identical except for four amino acid differences, and the absence of the c-terminal 61 amino acids of OAF075b. However, as shown

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<sup>1</sup> Labeled as "Attachment 1."

<sup>2</sup> Labeled as "Attachment 2."

<sup>3</sup> Labeled as "Attachment 3."

in Attachment 4, specific domains of CPA3 are maintained in OAF075b. This homology analysis supports the statement in the specification of the instant application that OAF075b and a human carboxypeptidase (A2) have significant homology, and are therefore expected to share activity (page 32, lines 13-18).

In view of the substantial homology between OAF075b and CPA3, Applicants assert that OAF075b has a function as a marker for prostate cancer or a marker for the treatment of prostate cancer. Furthermore, Applicants assert that the skilled artisan would clearly understand how to use the cDNAs recited in the claims for the disclosed utility.

As Applicants have identified a specific and substantial utility for the polypeptide encoded by the claimed cDNA, Applicants respectfully request reconsideration and withdrawal of this rejection.

### **III. Rejection of the Claims Under 35 U.S.C. §112**

A. At paragraph 4 of the Office Action, claim 3-7 are rejected under 35 U.S.C. §112, first paragraph, as lacking adequate written description.

The Examiner states that the claims are directed to any homologue, fragment, or homologue of the fragments of the polynucleotide sequences represented by SEQ ID NOs: 2, 3, 5, 7, 8, 10, 11, 13 and 14, as well as homologues, and fragments of homologues that hybridize to these sequences.

The Examiner asserts that none of these sequences meets the written description provisions of 35 U.S.C. §112. The Examiner explains that the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins. Further,

adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid sequence itself is required.

In response, Applicants include herewith amendments to the claims, such that all recitations of homologues, fragments, and homologues of fragments have been deleted from the claims. In view of these amendments, Applicants assert that the claims, as amended, find adequate written description support in the specification, and therefore respectfully request reconsideration and withdrawal of this rejection.

**B.** At paragraph 6 of the Office Action, claim 3-7 are rejected under 35 U.S.C. §112, second paragraph, as being vague and indefinite.

The Examiner states that because claim 3 depends on non-elected claim 1, the metes and bounds of the claims are vague and indefinite.

In response, Applicants note that claim 3 has been amended to convert it to an independent claim. Thus, the claim is now definite as written. In view of this amendment, Applicants respectfully request reconsideration and withdrawal of this rejection.

#### **IV. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. §1.111  
U.S. Appln. No. 09/700,397

Q61459

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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